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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,567	08/05/2003	A. Wesley Prais	102-523 DIV/CON/CIP II	6974
32752 7590 05/18/2007 DAVID W. HIGHET VP & CHIEF IP COUNSEL SECTION DICKINSON AND COMPANY 1 BECTON DRIVE MC 110 FRANKLIN LAKES, NJ 07417-1880			EXAMINER KOHARSKI, CHRISTOPHER	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 05/18/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/634,567

Applicant(s)

PRAIS ET AL.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 and 31-59 is/are pending in the application.
- 4a) Of the above claim(s) 11-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 19-28, 30-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges the amendment filed 3/15/2007 in which claims 28, 32-34 and 38 were amended and claims 29-30 being cancelled. A terminal disclaimer was filed 3/15/2007 for patents 5,752,942 and 6,629,963 are approved. Currently, claims 1-28 and 31-59 are pending for examination in this application with claims 11-18 withdrawn from a previous election restriction.

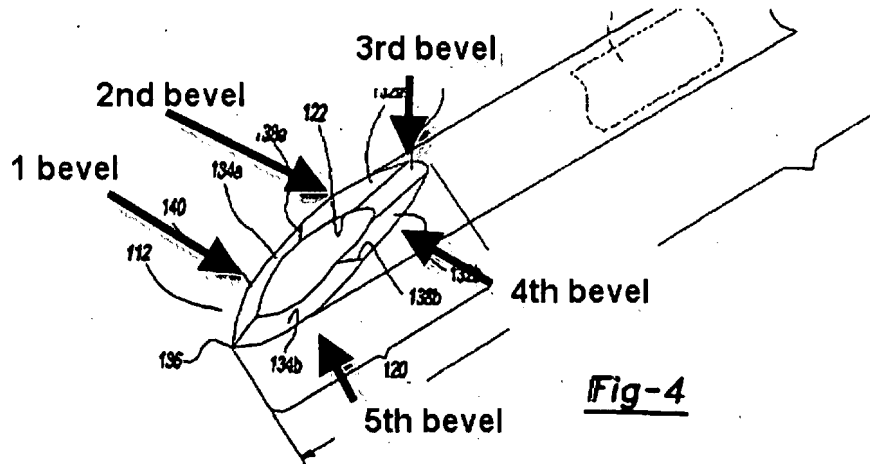
### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Amended claim 12 is unclear, the amendment recites "...said bevel..." in which the only antecedent basis mentions "...five bevels...", it is unclear to which bevel Applicant is referring to for in the amended claim text.

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Amended claim 38 is unclear, the amendment recites the different lengths of each bevel, the claimed lengths are unclear, and Examiner finds no support is Applicant's specification or drawings for the 1-5 bevels (i.e. labeled), following Applicant's terminology (claim 38 text) Examiner assumes (see Applicant's drawing below):



Examiner finds it unclear as to how the first and third bevels each have a length greater than each of said second, forth and fifth bevels. There is no support for the bevel characterization of each bevel (first-fifth), and the length characterization made by Applicant's representative.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

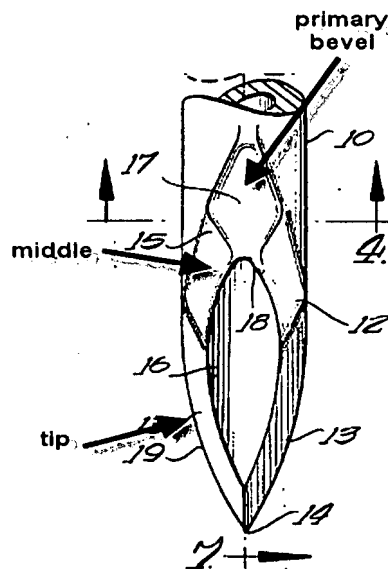
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 19-25, 28, 31-35 and 38-47 are rejected under 35 U.S.C 103(a) as being unpatentable over Baldwin et al. (3,071,135).

Regarding claims 1-8, 19-25, 28, 31-35 and 38-47, Baldwin et al. discloses a needle cannula comprising a needle (10) with a plurality of planar bevels with different angles relative to the central axis, with a primary bevel (17), a pair of tip bevels (13), and a pair of middle bevels (12) located intermediate to said tip bevel and primary bevel. Additionally the bevels angles with respect to the angles between the bevel angles each bevel has a distinct plane located a specific rotational angle with the planar angles of the primary and middle bevels being substantially equal (Figures 1-5) (see marked figure below).



Additionally, Baldwin et al. discloses multi-bevel point, said cannula having a central axis (along 14) and an outer and inner diameter, said needle cannula having a lumen (near 18) with an opening defining a point (14) with a first, second, third, fourth

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and fifth bevels (13, 19, 12, 15, 17)(Figures 1 and 3), said first bevel contiguously extending between said fifth and second bevels, said second bevel contiguously extending between said first and third bevels, said third bevel contiguously extending between said second and fourth bevels, said fourth bevel contiguously extending between said third and fifth bevels, and said fifth bevel contiguously extending between said fourth and first bevels, wherein said first and third bevels each have a greater length than each of said second bevel, said fourth bevel, and said fifth bevel (see Figures 1-4).

Baldwin et al. meets the claim limitations as described above except for a needle inner and outer diameter, cannula thickness, and bevel planar angle ranges as claimed by Applicant and syringe barrel.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the reference using Applicant's needle ranges, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Additionally, if not inherent (col 2, ln 45-70) it would be obvious to use the cannula hypodermic needle with a syringe barrel such as Hausser (5,385,555).

### ***Claim Rejections - 35 USC § 103***

Claims 50-57 are rejected under 35 U.S.C 103(a) as being unpatentable over De Luca.

Regarding claims 1-8, 19-25, 28-35 and 38-47, De Luca discloses a needle cannula comprising a needle (10) with a plurality of bevels with different angles relative

to the central axis, with a primary bevel (12), a pair of tip bevels (21,22), and a pair of middle bevels (23,24) located intermediate to said tip bevel and primary bevel.

Additionally the bevels angles with respect to the angles between the bevel angles each bevel has a distinct plane located a specific rotational angle (Figures 1-13).

De Luca meets the claim limitations as described above except for a needle inner and outer diameter, cannula thickness, and bevel planar angle ranges as claimed by Applicant and syringe barrel.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the reference using Applicant's needle ranges, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Additionally, if not inherent it would be obvious to use the cannula hypodermic needle with a syringe barrel such as Hausser (5,385,555).

### ***Claim Rejections - 35 USC § 103***

Claims 9-10, 26-27, 36-37, 48-49 and 58-59 are rejected under 35 U.S.C 103(a) as being unpatentable over Baldwin et al. (or De Luca) in view of Hausser (5,385,555). Baldwin et al. (or De Luca) meets the claim limitations as described above except for a needle shield with the specific Shore hardness's as claimed.

However, Hausser teaches a lockable safety shield for a hypodermic syringe.

Regarding claims 9-10, 26-27, 36-37, 48-49 and 58-59, Hausser teaches a needle shield (36) composed of a thermoplastic material (Figures 1-3).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the needle shield of Hausser with the needle shield material properties as claimed by Applicant, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

At the time of the invention, it would have been obvious to use the needle shield of Hausser with the needle of Baldwin et al. (or De Luca) because the needle shield aids in user safety and protection against needle sticks. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Hausser.

### ***Response to Arguments***

Applicant's arguments filed 3/19/2007 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Baldwin et al. (3,071,135) reference discloses does not disclose at least five planar bevels, planar angles be substantially equal, different rotational angles and side lengths; and that the De Luca (3,308,822) does not disclose a bevel located furthest from a point having a length shorter than any of said other ones. Examiner disagrees with Applicant's Representatives assertions, Baldwin et al. discloses a series of planar bevels (13, 19, 12, 15, 17)(Figures 1 and 3), Applicant has not claimed that the bevels are on the same plane or on a single plane, additionally, Applicant's own primary bevel is not on a



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singular plane but is claimed as a planar bevel; the rotational and planar angles of Baldwin et al.'s bevels are *substantially equal*; while defining the sides as claimed by Applicant, merely the first and third (13 (x2) bevels are of greater length than any other side, and if interpreted as argued by Applicant, Applicant's own disclosure is not supported (see above 112 rejection) and there is no criticality for the length of these bevels in Applicant's disclosure. Examiner asserts that the De Luca reference discloses a bevel (12) located furthest from a point having a length shorter than any of said other ones (16) as shown in Figure 8.

Additionally, the bevel angles and cannula materials are obvious since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960) and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (see above).

### ***Suggested Allowable Subject Matter***

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests the addition of a claim limitation drawn to the structure of the primary bevel (Figure 4, 130).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: 2,560,162.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

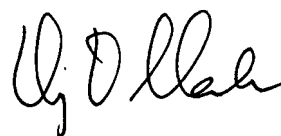
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

5/11/07

  
Christopher D. Koharski  
AU 3763

Primary Examiner.